Important Safety Notice

The FDA has required this safety notice as part of the AFREZZA REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers (HCPs) about the following serious risks of AFREZZA:

- **Risk of Acute Bronchospasm in Patients with Chronic Lung Disease.**
  - Counsel patients to inform their HCP if they have a history of lung disease
  - Do not use in patients with chronic lung disease

- **Appropriate Patient Selection.** AFREZZA is contraindicated in patients with:
  - Chronic lung disease such as asthma or chronic obstructive pulmonary disease (COPD)

- **Patient Evaluation Before Initiating Therapy.**
  - Before initiating, prescribers must perform a detailed medical history, physical examination, and spirometry (FEV1) in all patients, to identify potential underlying lung disease

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information on these risks, and a link to the Prescribing Information including the BOXED WARNING are available at [www.AfrezzaREMS.com](http://www.AfrezzaREMS.com).
**Indication**: AFREZZA (insulin human) Inhalation Powder is a rapid acting inhaled insulin indicated to improve glycemic control in adult patients with diabetes mellitus.

**Important limitations of use:**

- Not a substitute for long-acting insulin. In patients with type 1 diabetes, must use with a long-acting insulin
- Not recommended for the treatment of diabetic ketoacidosis
- Not recommended in patients who smoke or have recently stopped smoking

Please visit [www.AfrezzaREMS.com](http://www.AfrezzaREMS.com) for more information.

This letter does not contain the complete safety profiling for AFREZZA. Please see the Prescribing Information and Medication Guide, enclosed.

**Reporting Adverse Events**
You are encouraged to report negative side effects of prescription drugs to Sanofi US at 1-800-633-1610 and/or the FDA [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

Signature,

Charles Hugh-Jones, M.D.
Vice President and Chief Medical Officer, North America Pharmaceuticals
Sanofi US

Reference ID: 3734773